

In re Application of:
M. Von Herrath
Application No. 09/336,672
Filed: June 17, 1999
Page 3

PATENT
Attorney Docket No.: SCRIP1100

3. (Reiterated) The composition of claim 1, wherein the epitope is derived from insulin B-chain.
4. (Reiterated) The composition of claim 1, wherein the epitope is derived from myelin basic protein.
5. (Reiterated) The composition of claim 1, wherein the construct includes a plasmid backbone.
6. (Reiterated) The composition of claim 1, further comprising a nucleic acid sequence encoding a biological response modifier.

Sub B3
7. (Amended) The composition of claim 6 wherein the biological response modifier is selected from the group consisting of a cytokine, a chemokine, an interferon, ligands for lymphocyte receptors, and an interleukin.

A2
8. (Amended) The composition of claim 6 wherein the biological response modifier is selected from the group consisting of IL-1(alpha or beta), IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, IL-13, GM-CSF, M-CSF, G-CSF, LIF, LT, TGF-[.]beta[.], gamma-IFN (or alpha[.] or [.]beta[.] IFN), TNF-[.]alpha[.], BCGF, CD2, [or] ICAM and any combination thereof.

Sub C2
9. (Amended) The composition of claim 1, wherein the nucleic acid construct further comprises a regulatory element operatively linked to nucleic acid encoding the at least one epitope or the biological response modifier.

In re Application of:
M. Von Herrath
Application No. 09/336,672
Filed: June 17, 1999
Page 4

PATENT
Attorney Docket No.: SCRIP1100

10. (Reiterated) The composition of claim 9, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus, ALV, Cytomegalovirus (CMV) promoter, human Actin, human Myosin, RSV, human Hemoglobin, human muscle creatine and EBV.

B4
A3
11. (Amended) A method for treating or preventing autoimmune disorder in a subject having or at risk of having the disorder comprising administering to the subject[,] an immunomodulatory effective amount of a nucleic acid construct encoding at least one epitope from a self-antigen in a pharmaceutically acceptable carrier, wherein expression of the epitope in the subject [provides] generates a positive regulatory immune response, thereby treating or preventing the disorder.

12. (Reiterated) The method of claim 11, wherein the subject is a human.

Sub
B5
A4
13. (Amended) The method of claim 11, wherein the autoimmune disorder is selected from the group consisting of multiple sclerosis (MS), rheumatoid arthritis, systemic lupus [erythrematosis] erythematosus, type I diabetes, scleroderma, [myastenia] myasthenia gravis and ulcerative colitis.

14. (Reiterated) The method of claim 11, wherein the epitope is derived from insulin B-chain.

15. (Reiterated) The method of claim 11, wherein the epitope is derived from myelin basic protein.

In re Application of:
M. Von Herrath
Application No. 09/336,672
Filed: June 17, 1999
Page 5

PATENT
Attorney Docket No.: SCRI1100

16. (Reiterated) The method of claim 11, wherein the construct includes a plasmid backbone.
17. (Reiterated) The method of claim 11, further comprising administering to the subject a nucleic acid sequence encoding a biological response modifier.

18. (Amended) The method of claim 17, wherein the biological response modifier is selected from the group consisting of a cytokine, a chemokine, an interferon, ligands for lymphocyte receptors, and an interleukin.

95
Sub B7
19. (Amended) The method of claim 17, wherein the biological response modifier is selected from the group consisting of IL-1(alpha or beta), IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, IL-13, GM-CSF, M-CSF, G-CSF, LIF, LT, TGF-beta[.], gamma-IFN (or alpha[.] or [.]beta[.]-IFN), TNF-[.]alpha[.], BCGF, CD2, [or] ICAM and any combination thereof.

20. (Amended) The method of claim 11, wherein the nucleic acid construct further comprises a regulatory element operatively linked to nucleic acid encoding the at least one epitope or the biological response modifier.

21. (Reiterated) The method of claim 20, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus, ALV, Cytomegalovirus (CMV) promoter, human Actin, human Myosin, RSV, human Hemoglobin, human muscle creatine and EBV.

In re Application of:
M. Von Herrath
Application No. 09/336,672
Filed: June 17, 1999
Page 6

PATENT
Attorney Docket No.: SCRI1100

Sub B8
22. (Amended) A method for inducing a regulatory immune response in a subject having or at risk of having an autoimmune disorder comprising administering to the subject, an immunomodulatory effective amount of a nucleic acid construct encoding at least one epitope from a self-antigen in a pharmaceutically acceptable carrier, wherein expression of the epitope in the subject [provides] generates a positive regulatory immune response.

23. (Amended) The method of claim 22, wherein the autoimmune disorder is selected from the group consisting of multiple sclerosis (MS), rheumatoid arthritis, systemic lupus [erythrematosis] erythematosus, type I diabetes, scleroderma, [myastenia] myasthenia gravis and ulcerative colitis.

24. (Reiterated) The method of claim 22, wherein the epitope is derived from insulin B-chain.

25. (Reiterated) The method of claim 22, wherein the epitope is derived from myelin basic protein.

26. (Reiterated) The method of claim 22, wherein the construct includes a plasmid backbone.

27. (Reiterated) The method of claim 22, further comprising a nucleic acid sequence encoding a biological response modifier.

28. (Amended) The method of claim 27, wherein the biological response modifier is selected from the group consisting of a cytokine, a chemokine, an interferon, ligands for lymphocyte receptors, and an interleukin.

In re Application of:
M. Von Herrath
Application No. 09/336,672
Filed: June 17, 1999
Page 7

PATENT
Attorney Docket No.: SCRIP1100

Sub
Ab/Bio
Cont.

29. (Amended) The method of claim ~~22~~27, wherein the biological response modifier is selected from the group consisting of IL-1(alpha or beta), IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, IL-13, GM-CSF, M-CSF, G-CSF, LIF, LT, TGF-beta[.], gamma-IFN (or alpha[.] or [.]beta[.] IFN), TNF-[.]alpha[.], BCGF, CD2, [or] and ICAM.

30. (Reiterated) The method of claim 22, wherein the nucleic acid construct further comprises a regulatory element.

31. (Reiterated) The method of claim 30, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus, ALV, Cytomegalovirus (CMV) promoter, human Actin, human Myosin, RSV, human Hemoglobin, human muscle creatine and EBV.

Please add the following new claims:

Sub
Ca

--32. (New) The method of claim 11, wherein a single administration of the nucleic acid construct is effective to treat or prevent the disorder.--

Q7

--33. (New) The method of claim 22, wherein a single administration of the nucleic acid construct is effective to induce the regulatory immune response.—

Sub
Bio

--34. (New) The method of claim 11, wherein the positive immune response comprises induction of T-cells reactive to the autoantigen.--